JAN 2 8 2002

XIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Separate Page)

A. Submitter: Timothy Littlefield, Cranial Technologies Inc., 1395 West Auto Drive, Tempe, AZ 85284; phone 480-505-1840.

I. Classification: Class II.

II. Common or usual name: cranial orthosis, cranial band, helmet, molding helmet

III. Proprietary Name: DOC Band®

IV. Registration No.: 9027902

V. Classification Name: Cranial Orthosis, Code MVA, CFR 882.5970

VI. Performance standards: None; Special Controls required.

VII. Description: The DOC Band® is a cranial orthosis used to treat positional or deformational plagiocephaly in infants from 3 to 18 months of age. The devices works by applying a gentle holding pressure to the prominent regions of an infants' skull while leaving room for growth in the adjacent flattened regions.

The orthosis is made from a three-dimensional (3D) digital model of an infants' cranium acquired with the C3D - Cranial Imaging System™. This system was developed to capture an accurate, 3D image of an infants' head shape. It is based upon the well-established field of photogrammetry, and utilizes structured light and triangulated CCD cameras to digitally reproduce the 3D model. The system uses a noncoherent (i.e. non-laser light) light source, and captures a complete 3D image of the infants' head-shape, including the face and top of the head, in 1/180th of a second with an accuracy of +/- 0.5 mm. During acquisition, a 3D photograph of the child is also captured and precisely laid over the model for confirmation of the patient's identity. The digital model is then sent electronically to Cranial Technologies who creates a positive model using computer aided machining software and a 5-axis CNC mill. The positive model is then used to create the DOC Band, which is fit clinically and monitored as described in K-964992. Because the final fitting of the DOC Band is under the direct supervision of a carefully trained technician, the same safety aspects apply as in the original 510(k).

VIII. Labels and Labeling: Labels and labeling were included in Appendix II of K964992. Competitive labels were supplied in Appendix III of the original 510(k).

IX. Indications for Use: The DOC Band® is intended for medical purposes to apply pressure to prominent regions of an infants cranium in order to improve cranial symmetry and/or shape in

infants from 3 to 18 months of age, with moderate to severe nonsynostotic plagiocephaly, including infants with plagiocephaly-, brachycephalic-, and scaphocephalic-shaped heads. The C3D - Cranial Imaging System™ is used to improve the speed and accuracy of obtaining a 3D positive model of an infants' head.

X. Substantial Equivalence: The DOC Band® is substantially equivalent and virtually identical to the original DOC Band described in K964992, to later products such as K011350 cleared by Orthomerica Products and to other products cleared as substantially equivalent to this pioneering predicate device.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

XI. Clinical Discussion and Literature: Literature references and reprints showing the safety and effectiveness of this device when used under the Special Controls prescribed by the FDAwere provided in the original 510(k)--K964992.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2002

Timothy R. Littlefield
Director, Research and Development
Cranial Technologies, Inc.
1395 West Auto Drive
Tempe, AZ 85284

Re: K014012
Trade/Device Name: DOC Band
Regulation Number: 21 CFR 890.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: December 4, 2001
Received: December 5, 2001

Dear Mr. Littlefield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

XI. Indications for Use: [Separate Page]

510(k) Number: ~~NA~~ K014012

Device Name: DOC Band®

Indications for Use:

This device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Contraindications for use: Infants with synostosis or hydrocephalus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Division Sign-Off) Number K014012